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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61B 17/36

A1

(11) International Publication Number: WO 97/49345

(43) International Publication Date: 31 December 1997 (31.12.97)

(21) International Application Number: PCT/US97/11268

(22) International Filing Date: 27 June 1997 (27.06.97)

(30) Priority Data:
08/670,498 27 June 1996 (27.06.96) US

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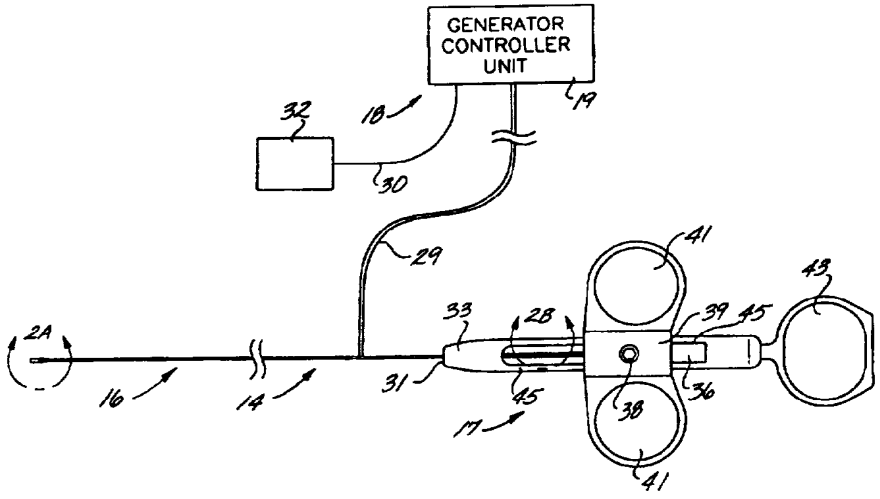
(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, US, UZ, VN, ARIPO patent (GH, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).

Published
With international search report.
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: TRANSCERVICAL ELECTROOCCLUSIVE STERILIZATION DEVICE



(57) Abstract

The present invention relates to a transcervical electrooccluslve sterilization device (16, 17) and methods of using such device. The transcervical electrooccluslve sterilization device (16, 17) comprises an electrode member (13) electrically detachably connected to a delivery member (14) and a power generator/controller unit (19). The electrode member is shaped to fit snugly inside a fallopian tube. The electrode member can be monopolar or bipolar. The electrode member has means for electrically and detachably connecting to the delivery member (14). The delivery member (14) generally comprises a handle means (17), an elongated body (16) connected to the handle means, and means for electrically and detachably connecting to the electrode means. Additionally, the delivery member has means for electrically connecting (29) the electrical member to a variable generator of alternating current. The generator/controller unit provides high frequency alternating current to the implantable electrode member via the delivery member. The transcervical electrooccluslve sterilization device is used by transcervically inserting the electrode member (13) into a fallopian tube using the delivery member.

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TRANSCERVICAL ELECTROOCCLUSIVE STERILIZATION DEVICE

FIELD OF THE INVENTION

The invention broadly relates to devices and methods for use in achieving permanent mammalian female sterilization. In particular, the invention relates to implantable electrodes capable of delivering electrocoagulative energy transcervically to the fallopian tube which causes desiccation, shrinkage and the eventual scarring of the fallopian tube wherein the electrode will adhere to the fallopian tube, and thus permanently block the fallopian tube.

BACKGROUND OF THE INVENTION

The most commonly used technique for human female sterilization is tubal ligation via laparoscopy or minilaparotomy. Both of these procedures are surgical in nature and therefore have risks associated with anesthesia and risks of injuring abdominal structures. Furthermore, both laparoscopy and minilaparotomy are unaffordable to many developing countries due to lack of facilities, equipment, and personnel.

A common veterinary technique for mammalian female sterilization is to spay the mammal. This technique is also surgical in nature and has the associated inherent risks of any surgical procedure.

A transcervical approach to female sterilization has long been considered to be potentially superior to surgical female sterilization. Utilizing natural passages that already exist in the female anatomy, the fallopian tubes can be accessed from the vaginal opening through the cervical canal of the uterus. Because no incision is necessary, such an approach is considered "nonsurgical" and usually does not require anesthesia. Because such an approach is theoretically safer and simpler to perform, it is potentially less expensive than the surgical approaches.

Many transcervical methods of female sterilization have been proposed and tried. These can be broadly divided into three categories based on the mechanism of tubal occlusion: (1) destruction of the interstitial portion of the fallopian tube by thermal energy (electrocoagulation, laser, liquid nitrogen, etc.); (2) delivery of sclerosing substances or tissue adhesives (quinacrine, tetracycline, phenol atrabine, methyl 2-cyanoacrylate, etc.); and (3) mechanical occlusive devices or plugs to block the fallopian tube (coil, hydrogel, ceramic plug, polyethylene plug, preformed silicone rubber plug, formed-in-place silicone plug, etc.). These methods are well summarized in Cooper, JM: Hysteroscopic Sterilization, *Clinical Obstetrics and Gynecology.* 35(2): 282-298, 1992, the disclosure of which is hereby incorporated by reference. Thus far, none of these methods has shown efficacy superior to surgical methods. Many of these methods fail to achieve an acceptable rate of fallopian tube

occlusion, achieve only temporary occlusion, or fail to remain inside the fallopian tube. In addition, some of the materials used in transcervical sterilization are chemical substances, such as quinacrine and methyl 2-cyanoacrylate, and their safety in terms of side effects and carcinogenicities are unknown.

While it has been shown that transcervical sterilization is potentially safer than conventional surgical sterilization, no such method with the appropriate efficacy and safety is presently available. Therefore, there exists a need for a sterilization device that is capable of occluding the fallopian tubes transcervically with high efficacy and minimal side effects. Such a device would make mammalian female sterilization easier, safer, and more affordable.

SUMMARY OF THE INVENTION

The present invention relates to a transcervical electroocclusive sterilization device and methods of using such device. The transcervical electroocclusive sterilization device comprises an implantable electrode member detachably connected to a delivery member and means capable of being electrically connected to a power generator/controller. The electrode member is shaped such that it will fit snugly inside a fallopian tube. The electrode member can be monopolar wherein the outer surface of the electrode member is electrically conductive. Alternatively, the electrode member can be bipolar wherein at least two distinct electrically conductive outer surfaces are separated by an electrically insulating material. The electrode member has means capable of being electrically connected to the power generator/controller. Also provided on the electrode member is means for detachably connecting the electrode member to the delivery member.

The delivery member generally comprises handle means, an elongated body connected to the handle means, and means for detachably connecting to the electrode member. Usually, the electrode member is electrically connected to the delivery member and the delivery member has means capable of being electrically connecting the power generator/controller member to provide the source of electroocclusive energy to the electrode member.

The generator/controller unit provides high frequency alternating current to the implantable electrode member via the electrical connection means. The generator/controller has a sensing circuit that monitors the impedance of the system. When the impedance increases, as it will when coagulation and carbonization occurs inside the fallopian tube, the power is automatically shut off.

The transcervical electroocclusive sterilization device of the present invention is used by transcervically inserting the electrode member into a fallopian tube using the delivery member. Typically the transcervical electroocclusive sterilization device is inserted into the intramural section of the fallopian tube. Electrical energy is then delivered to the electrode

using the electrical connection means and the generator/controller. As electrical energy is delivered to the fallopian tube, coagulation and carbonation of tissues adjacent to the electrode member begins. As this process continues, the adjacent tissues adhere to the electrode member. Eventually, the impedance of the circuit increases sharply indicating that the coagulation and carbonization process is complete. The electrical energy is discontinued and the electrode member is detached from the delivery member. The electrode member is thus left inside the coagulated and carbonized fallopian tube and serves as a permanent plug that prevents sperm from traveling through the fallopian tube to an ovum.

BRIEF DESCRIPTION OF THE DRAWINGS

The transcervical electroocclusive sterilization device will be described with reference to the figures wherein:

FIG. 1 is a cross sectional view of a female uterus and fallopian tube with a transcervical electroocclusive sterilization device inserted transcervically and the electrode member is located within the intramural fallopian tube;

FIG. 2 is a plan view of a transcervical electroocclusive sterilization device;

FIG. 2A is a plan view of the distal end of the transcervical electroocclusive sterilization device of FIG. 2 taken at circle 2A;

FIG. 2B is a plan view of a section of the control handle member taken at circle 2B;

FIG. 3 is a plan view of the electrode member of the transcervical electroocclusive sterilization device of FIG. 2;

FIG. 4 is a proximal end view of the electrode member of FIG. 3 taken along line 4-4;

FIG. 5 is a partial cross sectional view of the detachable connection means of the delivery member of the transcervical electroocclusive sterilization device of FIG. 2;

FIG. 6 is a perspective view of an alternate electrode member;

FIG. 7 is a plan view of the delivery member for the electrode member of FIG. 6;

FIG. 8 is a distal end view of the delivery member of FIG. 7 taken along line 8-8;

FIG. 8A is a cross sectional view of the delivery member of FIG. 7 taken along line 8A-8A;

FIG. 9 is a longitudinal cross sectional view of the delivery member of FIG. 7 while the graspers are open;

FIG. 10 is a longitudinal cross sectional view of the delivery member of FIG. 7 while the graspers are closed;

FIG. 11 is a further embodiment of an electrode member;

FIG. 12 is a cross sectional view of the electrode member of FIG. 11;

FIG. 13 is a schematic view of the delivery member for the electrode member of FIG. 11;

FIG. 14 is yet another embodiment of an electrode member of the present invention;

FIG. 15 is a proximal end view of the electrode member of FIG. 14 taken along line 15-15;

FIG. 16 is a plan view of the delivery member for the electrode member of FIG. 14;

FIG. 17 is a distal end view of the delivery member of FIG. 16 taken along line 17-17;

FIG. 18 is a plan view of a further electrode member;

FIG. 19 is a plan view of yet a further electrode member;

FIG. 20 is a plan view, partially in cross section, of another embodiment of a transcervical electroocclusive sterilization device;

FIG. 21 is a schematic view of the delivery member of FIG. 20;

FIG. 22 is a plan view of still a further delivery member;

FIG. 23 is a plan view, partially in cross section of the delivery member of FIG. 22 in a retracted position;

FIG. 23A is a plan view, partially in cross section of the delivery member of FIG. 22 in a partially extended position;

FIG. 23A is a plan view, partially in cross section of the delivery member of FIG. 22 in a fully extended position;

FIG. 24 is a cross sectional view of the corresponding electrode member for the delivery member of FIG. 22;

FIG. 25 is a plan view of yet a further electrode member;

FIG. 26 is a plan view of still a further embodiment of a transcervical electroocclusive sterilization device of the present invention with an electrolytic junction;

FIG. 27 is a cross sectional view of the embodiment of FIG. 26 taken along line 27-27; and

FIG. 28 is a plan view of yet a further embodiment of a transcervical electrooclusive sterilization device of the present invention.

DETAILED DESCRIPTION

Referring now to FIG. 1, a cross section of a female uterus U and a fallopian tube FT is generally illustrated. The cervix C is located at the opposite end of the vaginal opening (not shown). The cervical canal CC is in communication with the vagina V and the hollow uterine cavity. At the fundus F of the uterus are the two fallopian tubes, one on each side. The fallopian tubes are anatomically divided into four regions as the fallopian tube makes its way from the uterus to the ovary O, the intramural IM, the isthmus IS, the ampulla A, and the

infundibulum IN. The intramural region is the region of the fallopian tube that traverses the thick muscle wall of the uterus and is the presently preferred site for performing the electroocclusion of the present invention, although other regions of the fallopian tube could also be utilized.

Generally, a transcervical electroocclusive sterilization device 11 of the present invention is used to occlude the fallopian tube via a transcervical approach, with or without imaging guidance such as endoscopy, fluoroscopy, ultrasound imaging, or other imaging modalities. There are two basic designs of the transcervical electroocclusive sterilization device: bipolar and monopolar. Each will be described in detail below.

Referring now to FIG. 2, the transcervical electroocclusive sterilization device of the present invention comprises three main parts: an implantable electrode member 13, a delivery member 14, and a power generator/controller member 18. As used throughout the description, proximal will refer to locations near a hand of an operator of the device and distal will mean a location away from the hand of the operator of the device. The electrode member 13 illustrated in FIGS. 2, 2A, 3, and 4 is a monopolar electrode. The electrode member is made out of any suitable biocompatible electrically conducting substance such as surgical stainless steel, platinum, platinum iridium alloy, tungsten, gold, or the like. Alternatively, the electrode member is made out of a plastic material such as polyurethane, polyvinyl chlorine, Teflon or the like or a ceramic material and then either coated on its outer surface with an electrically conductive material or a tightly wound electrically conductive coil is adhered to the outer surface. The electrode member is generally cylindrically shaped (although this can vary as described below) such that it will fit inside a fallopian tube. The electrode member has a cylindrical body 51 and a proximal cylindrical stem 53. In the preferred embodiment, the cylindrical body is about 7 mm long and about 3 mm wide, however other dimension can also be used. The cylindrical stem in the preferred embodiment is about 2 mm long and about 2 mm wide.

The delivery member illustrated in FIGS. 2, 2A, 2B and 5 is a modified commercially available grasper that has a power/controller member 18 electrically connected to it. The grasper is commercially available from numerous manufacturers. One particular useful grasper is the Flexible Endoscopic Forceps manufactured by Neuro Navigational Corp. in Costa Mesa, California. The grasper comprises three main sections, a distal grasping section 15, a body section 16, and a proximal handle section 17. Except for the handle section, the grasper is made out of electrically conductive surgical stainless steel. The handle section is made out a suitable plastic material such as polycarbonate. The grasper section (better illustrated in FIGS. 2A and 5) comprises a top grasper 25 pivotally connected to a bottom grasper 27 via a pivot pin 71. The pivot pin 71 is additionally connected to two housing arms

24 extending distally from the grasper housing 23 such that the graspers have only rotational freedom about the pivot pin and is spatially fixed in relation to linear position to the housing. The graspers are provided with a plurality of teeth 73 to grab the stem of the electrode member. The top and bottom graspers are respectively pivotally connected to pivot hinges 65 and 63 via pivot pins 69 and 67. These pivot pins are not connected to the grasper housing and thus provide points for linear motion as well as rotational motion. The two pivot hinges are connected to a pivot pin 61 which in turn is connected to a stainless steel puller wire 37. The graspers are located within two arms 24 of the grasper housing 23. (In FIG. 5 only one arm 24 is shown to illustrate the components of the graspers.) Both arms extend distally from the grasper housing and are made from a unitary hollow cylinder and are electrode discharge machined to create two groves 26 on the top and bottom of each arm.

The grasper housing 23 has a reduced proximal diameter section 75 that is welded to a distal end of a noncompressible coil 21. The noncompressible coil is hollow with the puller wire 37 traveling through the longitudinal axis of the coil. The noncompressible coil is about 50 cm long and about 3 mm wide. The coil provides the graspers with flexibility, but also provides the graspers with compression resistance such that linear translation of the puller wire relative to the coil will open or close the graspers.

The proximal end of the stainless steel noncompressible coil is permanently attached to the distal end 31 of a plastic plunger 45 in the plastic handle section 17 (See FIG. 2). The handle section comprises a thumb hole 43 connected to the plunger which is slidably retained within a plastic housing 39. The housing comprises two mirror image parts that are connected via a screw 38. Connected to each side of the housing are finger holes 41. The stainless steel puller wire 37 passes through the distal end of the plunger and is permanently attached to the housing. Thus, by translating the plunger relative to the housing, the puller wire is translated relative to the noncompressible coil and the graspers open or close depending on the direction of the translation. The plunger has an internal opening 36. Situated within the distal hollow shaft is a stainless steel compression spring 35 (see FIG. 2B). The compression spring 35 provides force to the housing relative to the distal end of the plunger such that the housing is normally forced proximally. Thus, the graspers are normally in a closed position and the operator of the device must provide force to overcome the force of the compression spring to translate the handle distally relatively to the plunger to open the graspers.

A wire 29 electrically connects the compression coil of the delivery member to the generator/controller member. The generator/controller member comprises a source of variable alternating current to wires 29 and 30. Wire 30 is connected to a ground to be placed on or in the mammal near the fallopian tubes. The ground could be a transdermal patch 32 as

illustrated in FIG. 2 or it could be an electrically conductive surface placed within the mammal in the vagina, or uterus near the fallopian tube. One such surface could be an electrode attached to the outer surface of an introducing cannula that introduces the transcervical electroocclusive sterilization device into the uterus.

The generator/controller member provides high frequency alternating current to the electrode member via the stainless steel components of the delivery member. The generator/controller member has a sensing circuit that monitors the impedance of the system. When the impedance increases, as it will when coagulation and carbonization occurs inside the fallopian tube, the power is automatically shut off. The frequency of the output should be above 10,000 Hz so as not to cause muscle contraction. The frequency could go up to the MHZ range. The shape of the alternating current can be sinusoidal, square, triangular, etc. The intervals can be continuous, pulsatile, etc. Power output can be from 0.1 watt to 100 watts. In the currently preferred embodiment, the frequency is 450 KHz the shape of the wave is sinusoidal and the power varies depending on the electrode and the mammal, but typically ranges from 10-50 watts. The generator can be powered by batteries or by a standard alternating current electrical outlet. A suitable commercially available generator/controller is a combination of the CFG280 Signal Generator by Tektronix of Beaverton, Oregon and the 75A220 Amplifier by Amplifier Research of Souderton, Pennsylvania.

In use, the stem of the monopolar electrode member is placed inside the graspers of the delivery member. The generator/controller member is electrically connected to a stainless steel portion of the delivery member and the ground is connected to the mammal near the fallopian tubes. The electrode member is placed in the fallopian tube lumen through the vaginal opening and the cervical canal of the mammal. This can be done with or without imaging guidance such as fluoroscopy, endoscopy, ultrasound imaging, etc. Currently, the preferred location is within the intramural region of the fallopian tube, however other locations within the fallopian tube could also be used. Once the electrode member is in place, the generator/controller member is activated by the operator and high frequency alternating current is delivered to the fallopian tube. Once coagulation, carbonization, and adhesion of the electrode member to the inner wall of the fallopian tube has occurred, the power is automatically shut off by the unit. At this point, the operator opens the graspers by using the control handle and releases the electrode member from the delivery member. The delivery member is then removed from the mammal. This leaves the electrode member within the electrically scarred fallopian tube to serve as a permanent barrier to fertilization.

Turning now to FIGS. 6-10, an alternate configuration of a transcervical electroocclusive sterilization device is illustrated. This embodiment has a bipolar electrode

member 13A such that a separate ground is not needed and the electric energy is delivered to the fallopian tubes without traversing through other tissues.

The bipolar electrode member comprises a cylindrical electrically insulating material 111 such as silicone, ceramic, Teflon, polyurethane, polycarbonate or any other suitable non-conductive biocompatible material. Attached to the outer surface of the insulating material are two electrode helical coils 105 and 107. The electrode helical coils can be made out of a variety of biocompatible electrically conductive materials such as tungsten, gold, platinum, platinum iridium alloy, or the like. The coils are connected to the ceramic insulating material via welding, glue, epoxy, etching, or the like. The two helical coils are parallel to each other and do not touch each other.

At the proximal end of the electrode member is a stem comprising two half stems 101 and 103 separated by a channel 109. The two half stems are welded with a nonconducting welding material such as polyurethane inside a cylindrical hole 102 of the insulating material. The channel 109 is filled with a nonconducting filling material 104 inside the hole to help stabilize the stem. The nonconductive filler material can be any suitable insulating material such as epoxy, polyurethane, or the like.

FIGS. 7-10 illustrate the delivery member 14A and power generator/controller member 123 for the electrode member of FIG. 6. The delivery member has three main sections: a handle section 17A, an elongated body section 16A, and a bipolar grasper section 15A. The handle section comprises a plastic thumb hole 113 that is connected to the proximal end of a translation rod 115. The translation rod is preferable a thick (about 1 mm diameter) stainless steel wire, however other materials such as nitinol, plastics or the like could also be used. The translation rod is slidably retained within a hollow flexible tube 117 and protrudes through a central opening in distal end cap 118 attached to the distal end of the hollow tube such that the proximal end of the translation rod extends out of the proximal end of the hollow tube. The hollow tube can be made out of any suitable electrically nonconductive flexible material such as polyurethane, catheter extrusions, or the like. Fixed to outside of the hollow tube is a plastic attachment ring 119 that has two finger holes 121.

Within the hollow tube 117 (see FIGS. 9 and 10) is a compression spring 141. The compression spring exerts force between the internal hollow tube rest 139 connected to the inner surface of the hollow tube and the translation rod rest 137 connected to the translation rod such that the normal resting position (see FIG. 10) is with the translation rod rest 137 forced against the end cap 118 which in turn caused the graspers 129 and 131 to be closed.

Welded to a side port 143 in the hollow tube 117 is an electric cable 125 that is connected to the power generator/controller member 123. Internally within the hollow tube is another electric cable 145 which has at least two insulated wires 147 and 149. As will be

detailed below, each wire is electrically connected to a grasper. The electric cable 145 travels within the hollow lumen of the flexible tube (see FIG. 8A).

The translation rod 115 travels along the longitudinal axis of the hollow tube within the hollow tube's lumen. Attached to the distal end of the translation rod is a rectangular insulator 133 which has a top surface 134 and a bottom surface 136 (see FIG. 8). Attached to the top surface of the insulator is a top grasper 129 and attached to the bottom surface of the insulator is bottom grasper 131. The top and bottom graspers are retained in relative position to each other and the insulator by a rigid nonconducting retaining ring 135. The top and bottom graspers are made out of a malleable electrically conductive material such as annealed stainless steel. The top grasper is eclectically connected to one of the wires 147 of the electric cable 145 and the other wire 149 is electrically connected to the bottom grasper. The insulator and retaining ring are made out of an electrically insulating material such as reinforced polycarbonate or the like.

The graspers are made out of a malleable material such that they are flexible but normally retain their natural shape. This way, when the graspers are free from the confines of the hollow tube (see FIG. 9), the graspers are open. At the distal end of the hollow tube is a reinforcement ring 127. The reinforcement ring 127 provides the hollow tube with enough strength and rigidity such that the graspers will close when the graspers are within the confines of the distal end of the hollow tube (see FIG. 10). As mentioned above, the compression spring 141 exerts enough force such that the graspers are normally closed.

The embodiment of FIGS. 6-10 is used by translating the translation rod distally relative to the hollow tube to open the graspers. The electrode member is then inserted into the graspers such that the insulator 133 is inserted into the channel 109 of the stem of the electrode member, the top grasper clamps down on the top half stem of the electrode member and the bottom grasper clamps down on the bottom half stem of the electrode member. This provides a distinct electrical connection to each helical electrode. The electrode member is then transcervically positioned into place within a fallopian tube similarly as previously described using the delivery member. The operator then turns on the power generator/controller member to coagulate and carbonize the tissues around the electrode member. The tissues adhere to the electrode member and the electrode member is released from the delivery member to form a permanent occlusive barrier to fertilization. Finally, the delivery member is removed.

FIGS. 11-12 illustrate an alternate bipolar electrode member 13B which is three hollow cylinders welded together. The proximal hollow cylinder 151 is made out of an electrically conductive material such as stainless steel. The middle hollow cylinder 153 is made out of an electrically insulating material such as polyurethane. The distal hollow

cylinder 151 is also made out of an electrically conductive material. The distal end of the distal cylinder is filled with a filer material 159 such that the electrode member does not have a passage way for sperm or ova to travel. The filler material could be any suitable filler material such as epoxy, polyurethane, or the like. Alternately, the filler material could be the same material as the distal hollow cylinder.

The delivery member (see FIG. 13) comprises a hollow outer tube 171 with an electrically insulating rod 163 slidably retained in the hollow tube. The hollow tube is preferably electrically insulating and constructed out of polyurethane, catheter extrusion or the like. The rod is constructed out of a plastic material, polyurethane coated stainless steel, or the like. The proximal end of the rod is connected to a control ring 161. An electric cable 173 with at least two wires 175 and 177 travel within the rod. At the proximal end of the rod, the electric cable 173 is connected to cable 167 which is in turn connected to power generator controller member 165. At the distal end of the rod two electrically conductive rings are secured to the outside of the rod using glue. The distal ring 183 is electrically connected via solder 178 to wire 177 and its length corresponds to the hollow length within the distal cylinder of the electrode member. The proximal ring 179 is electrically connected via solder 176 to wire 175 and its length corresponds to the hollow length within the proximal cylinder of the electrode member. The two rings are spaced apart to insulate each one from the other. The spacing is the same length as the middle insulating cylinder of the electrode member.

The embodiment of FIGS 11-13 is used by sliding the electrode member over the distal end of the rod of the delivery member such that ring 183 contacts cylinder 155 and ring 179 contacts ring 151. The electrode member is placed transcervically into a fallopian tube of a mammal as described above and electrical energy is delivered via the power generator/controller. Once the tissues have adhered to the electrode member, the electrode member is released in place by pulling the rod proximally relative to the hollow tube. Finally, the delivery member is removed from the mammal.

FIGS. 14-17 illustrate yet a further bipolar embodiment of the present invention wherein the electrode member 13 C comprises two electrically conductive half cylinders 209 and 213 connected to a central insulating material 211. The proximal end of the electrode member has a square opening 210. The deliver member 14C is similar to the deliver member illustrated in FIG. 13 except the distal end of the rod 223 is connected to a square peg comprising a top electrically conductive rectangular piece 227, a rectangular electrically insulating piece 229 and a bottom rectangular electrically conductive piece 231. The square peg fits within the square hole 201 of the electrode member such that an electrical connection is made between the top rectangular piece 227 and the top half cylinder 209 and an electrical connection is made between the bottom rectangular piece 231 and the bottom half cylinder

213. Electrode lead wires (not illustrated) traverse through the rod to an electric cable (not illustrated) connected to the power generator/control member (not illustrated) wherein each rectangular piece would be in distinct electric connection with the power generator. This embodiment would be used similarly to the embodiment of FIGS. 11-13 such that once the tissues have adhered to the electrode member, the electrode member is released in place by pulling the rod proximally relative to the hollow tube to pull the square peg out of the square hole. Finally, the delivery member is removed from the mammal.

The embodiments described so far all have smooth cylindrically shaped electrode members. However, other shapes could be used such as a conical shape, a barrel shape, a dumbbell shape, etc. An essential feature of the electrode member is that the electrode member provides a mechanical barrier to sperm and ova. Thus, the electrode member cannot have a passageway along its interior. Most of the electrode members are completely solid, however, as long as there is no free communication from the proximal to the distal end of the electrode member the electrode member can serve as a useful mechanical barrier.

FIG. 18 illustrates a conically shaped monopolar electrode member 13D that has a conically shaped body 251 and a cylindrical stem 253. Additionally, the surface of the electrode member does not need to be smooth, channels and contours could be provided to enlarge the surface area and to enhance tissue adhesion to the surface of the electrode member which prevents incidental movement of the electrode member. FIG. 19 illustrates an electrode member 13E with a conically shaped body 261 that has a plurality of grooves 262 around the body's outer surface and a cylindrical stem. FIG. 25 illustrates an electrode member comprising a string of spherical metallic balls 351 welded together via metallic welds 353. The gaps between the balls allow for the tissue to contract around each ball and form a tight seal to the electrode member.

There also could be many different types of delivery members with many different means for detachably connecting to electrode members. Another means for detachably connecting an electrode member 13F to a delivery member 14F is illustrated in FIGS. 20-21 wherein the electrode member is a monopolar electrode 271 which has a conically shaped proximal opening 289 which leads to a spherical chamber 285. The delivery member comprises a hollow tube 277 with a rod 275 traversing through the tube. At the proximal end of the rod is a control ring 273. At the distal end of the rod is a forked member wherein the top fork 287 is connected to a top half sphere 279 and the bottom fork 283 is connected to a bottom half sphere 281. The half spheres are initially within the spherical chamber of the electrode member. Once the electroocclusive procedure is finished, the electrode is released in place by pushing the hollow tube distally to the electrode member and translating the rod proximally relative to the tube. This forces the half spheres together and they retract into the

tube (see FIG. 21). Once the half spheres are retracted within the hollow tube, the delivery member can be removed from the mammal.

Another means for detachably connecting the electrode member to the delivery member is illustrated in FIGS. 22-24. In this embodiment the delivery member has a hollow tube 307 with a plunger 303 traversing through the tube. At the proximal end of the plunger is a thumb rest 301. At the proximal end of the hollow tube are two finger rests 305. Provided near the distal end of the hollow tube are two grooves 315 and 317. Attached near the distal end of the plunger are two tension loaded wings 309 and 311 which fit within the grooves in the tube. The tension loaded wings slope outward towards the proximal end of the groves. The very distal end 313 of the plunger extends slightly distally from the distal end of the tube. As illustrated in FIGS. 23, 23A, and 23B, translating the plunger distally relative to the tube translates the distal end 313 out from the tube and the wings begin to retract within the tube. Once the plunger is completely translated distally, the wings are fully retracted within the distal end of the hollow tube. The electrode member 13G (see FIG. 24) is a monopolar cylindrical electrode 321. A cylindrical channel 323 is provided at the proximal end of the electrode. Midway in the cylindrical channel are two apertures 325 and 327 shaped like the wings of the delivery member such that the wings fit within the apertures. In use, the electrode member is loaded over the distal end of the delivery member and the wings of the delivery member expand to fit through the grooves in the hollow tube into the apertures of the electrode member. After the electroocclusive procedure, the electrode member is released in place by translating the plunger distally relative to the tube to retract the wings within the tube and release the electrode member. The delivery member is then removed from the mammal

FIGS. 26 and 27 illustrate yet a further embodiment of a transcervical electroocclusive sterilization device of the present invention. The electrode member 13G is a cylindrical monopolar electrode 361. The delivery member is a flexible rod 367 contained within a hollow introducing catheter 369. The flexible rod is constructed out of an electrically insulating material such as an extrusion of polyurethane. Within the center of the rod and running axially through the entire length of the rod is an electrode lead wire 381. The electrode lead wire 381 is connected to an electrolytic junction lead 363 which connects the distal end of the electrode lead wire to the electrode member. The electrolytic junction lead 363 is preferably made out of relatively thin steel wire. A second lead wire 383 is disposed within the rod near the outer diameter of the rod. This lead wire is connected to a ring electrode on the outside of the distal end 364 of the rod. At the proximal end of the rod, the two lead wires 381 and 383 are placed within a cable 375 and connected to the generator/controller member (not shown).

The introducing catheter is a standard commercially available introducing catheter comprising a hollow elongated distal body 369, a hollow elongated proximal body 373, a Y junction 371 connecting the proximal and distal bodies, and a lure fitting 377 connected to the angled Y port. The introducing catheter has a central lumen 379 which the flexible rod is inserted.

In use, the distal end of the introducing catheter is transcervically placed within the uterus of a mammal. The electrode member attached to the flexible rod via the electrolytic junction is inserted into the lumen of the catheter and advanced into the uterus. The electrode member is then advanced into the intramural region of a fallopian tube and the distal end of the flexible rod is just inside the opening to the fallopian tube. This way, the ring electrode attached to the outside of the distal end of the fallopian tube is in contact with the uterine tissues which forms the fallopian tube opening. Alternating current is then delivered to the electrode member and the ring electrode via the generator/controller to coagulate and carbonize the fallopian tube. The alternating current is shut of once the impedance increases. the alternating current is shut off, however, the electrode member is still attached to the delivery member.

The electrode member is detached from the delivery member by providing to the electrolytic junction lead direct current and saline solution to dissolve the steel wire. This is accomplished by attaching a saline irrigation source to the lure fitting of the Y junction of the introducing catheter and allowing saline to flow to the electrode member. Direct current is then applied to the electrode member and ring electrode via the generator/controller member. After about 1 to about 10 minutes, the steel electrolytic junction lead will disintegrate and the electrode member will be freed from the delivery member. The delivery member and introducing catheter is then removed from the mammal.

FIG. 28 illustrates yet another embodiment of the present invention. Only the distal end of the unipolar electrode 401 and the delivery catheter 403 are illustrated, the proximal end of the delivery catheter could be substantially similar to previously described embodiments. The electrode 401 comprises a solid distal end 405 and a coiled electrode 407 with a natural threaded surface. The distal end of the delivery catheter comprises a distal non electrically conducting shaft 409 with the very distal end being covered with an electrically conducting surface 411. Protruding from the sides of the electrically conducting surface are a plurality of electrically conducting spheres 413 attached the conducting surface via electrically conducting shafts 415. The spheres are spaced apart to fit within the natural threads of the electrode. A lead wire is electrically connected to the conducting surface within the delivery catheter. The proximal end of the delivery catheter is provided with means for connecting the lead wire to an RF generator/controller. The electrode of Fig. 28 is

used by placing the electrode withing the area of the fallopian tube to be occluded, delivering the needed RF energy to the unipolar electrode to cause the fallopian tube to desiccate, carbonize, constrict, and then adhere to the electrode, rotating the delivery catheter appropriately to "unscrew" the electrode from the delivery catheter to thereby leave the electrode within the fallopian tube and occlude the tube via the solid distal end of the electrode.

Thus, a transcervical electroocclusive sterilization device is disclosed which allows for transcervical introduction into a fallopian tube of an implantable electrode member which coagulates and carbonates the fallopian tube. The electrode member is then left in place within the fallopian tube to serve as a permanent barrier to fertilization. While embodiments and applications of this invention have been shown and described, it would be apparent to those skilled in the art that many more modifications are possible without departing from the inventive concepts herein. The invention, therefore, is not to be restricted except in the spirit of the appended claims.

WHAT IS CLAIMED IS:

1. A transcervical electroocclusive sterilization device comprising:

a delivery member;

an electrode member with an electrically conducting outer surface electrically and detachably connected to the delivery member; and

a source of electrical energy connected to the delivery member with electrical connection with the electrode member.

2. The transcervical electroocclusive sterilization device of claim 1 wherein the electrode member is a monopolar electrode.

3. The transcervical electroocclusive sterilization device of claim 1 wherein the electrode member is a bipolar electrode.

4. The transcervical electroocclusive sterilization device of claim 1 wherein the electrode member is cylindrically shaped.

5. The transcervical electroocclusive sterilization device of claim 1 wherein the electrode member is conically shaped.

6. The transcervical electroocclusive sterilization device of claim 1 wherein the delivery member comprises graspers for grasping the electrode member.

7. The transcervical electroocclusive sterilization device of claim 1 wherein the delivery member comprises a plunger for releasing the electrode member.

8. The transcervical electroocclusive sterilization device of claim 1 wherein the delivery member comprises an electrolytic junction wherein when direct current is applied to the electrolytic junction the electrolytic junction disintegrates.

9. The transcervical electroocclusive sterilization device of claim 1 wherein the delivery member comprises a distal end and a proximal end and a handle means is connected to the proximal end and a detachable connection to the electrode member is connected to the distal end.

10. The transcervical electroocclusive sterilization device of claim 6 wherein the delivery member further comprises two graspers, an insulator separating the two graspers, an electric lead wire attached to each grasper and to the electric energy source, and wherein the electrode member comprises an insulating material with bipolar electrodes at the outer surface of the insulating material wherein each grasper is in electrical connection with each electrode.

11. A transcervical electroocclusive sterilization device comprising:
a delivery member with proximal and distal ends, the delivery member comprising:
a proximal handle section;
an elongated body section; and
a distal detachable connection section; and
an electrode member with an electrically conducting outer surface electrically and detachably connected to the detachable connection section wherein the electrode member is capable of being connected to a source of electrical energy via the delivery member.

12. The transcervical electroocclusive sterilization device of claim 11 wherein the electrode member is a monopolar electrode.

13. The transcervical electroocclusive sterilization device of claim 11 wherein the electrode member is a bipolar electrode.

14. The transcervical electroocclusive sterilization device of claim 11 wherein the electrode member is cylindrically shaped.

15. The transcervical electroocclusive sterilization device of claim 11 wherein the electrode member is conically shaped.

16. The transcervical electroocclusive sterilization device of claim 11 wherein the delivery member comprises graspers for grasping the electrode member.

17. The transcervical electroocclusive sterilization device of claim 11 wherein the delivery member comprises a plunger for releasing the electrode member.

18. The transcervical electroocclusive sterilization device of claim 11 wherein the delivery member comprises an electrolytic junction wherein when direct current is applied to the electrolytic junction the electrolytic junction disintegrates.

19. The transcervical electroocclusive sterilization device of claim 11 wherein the delivery member comprises a distal end and a proximal end and a handle means is connected to the proximal end and a detachable connection to the electrode member is connected to the distal end.

20. The transcervical electroocclusive sterilization device of claim 11 wherein the electrode member comprises a plurality of spherical balls connected to each other.

21. A method of performing a transcervical sterilization procedure comprising:

transcervically inserting a solid electrode member with an outer conductive surface into a lumen of a fallopian tube;

applying electric energy to the electrode member to thereby coagulate and carbonize surrounding tissue and adhere the surrounding tissue to the electrode member; and

releasing the electrode member in place in the lumen of the fallopian tube wherein the electrode member serves as a barrier to sperm reaching an ovum.

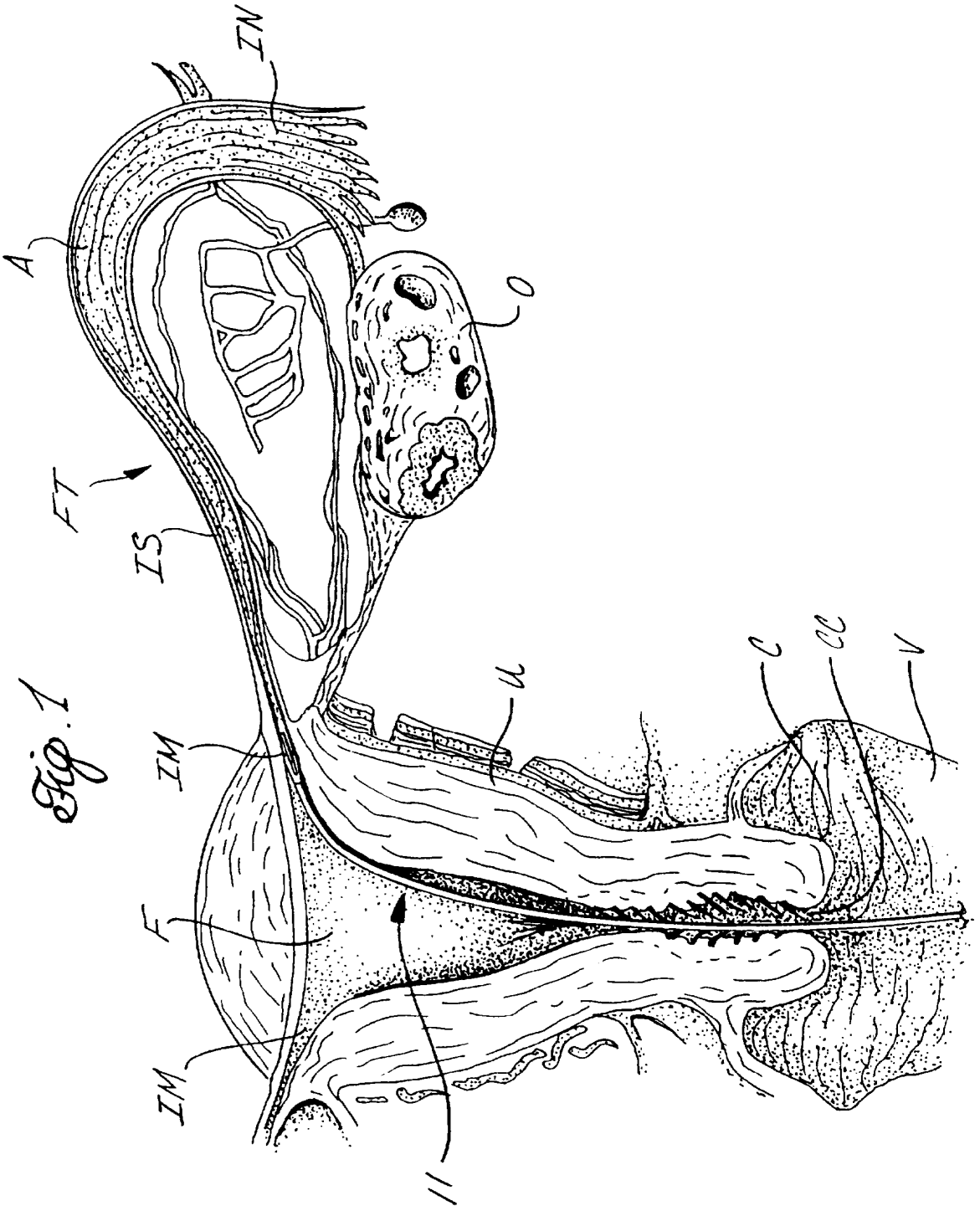


Fig. 1

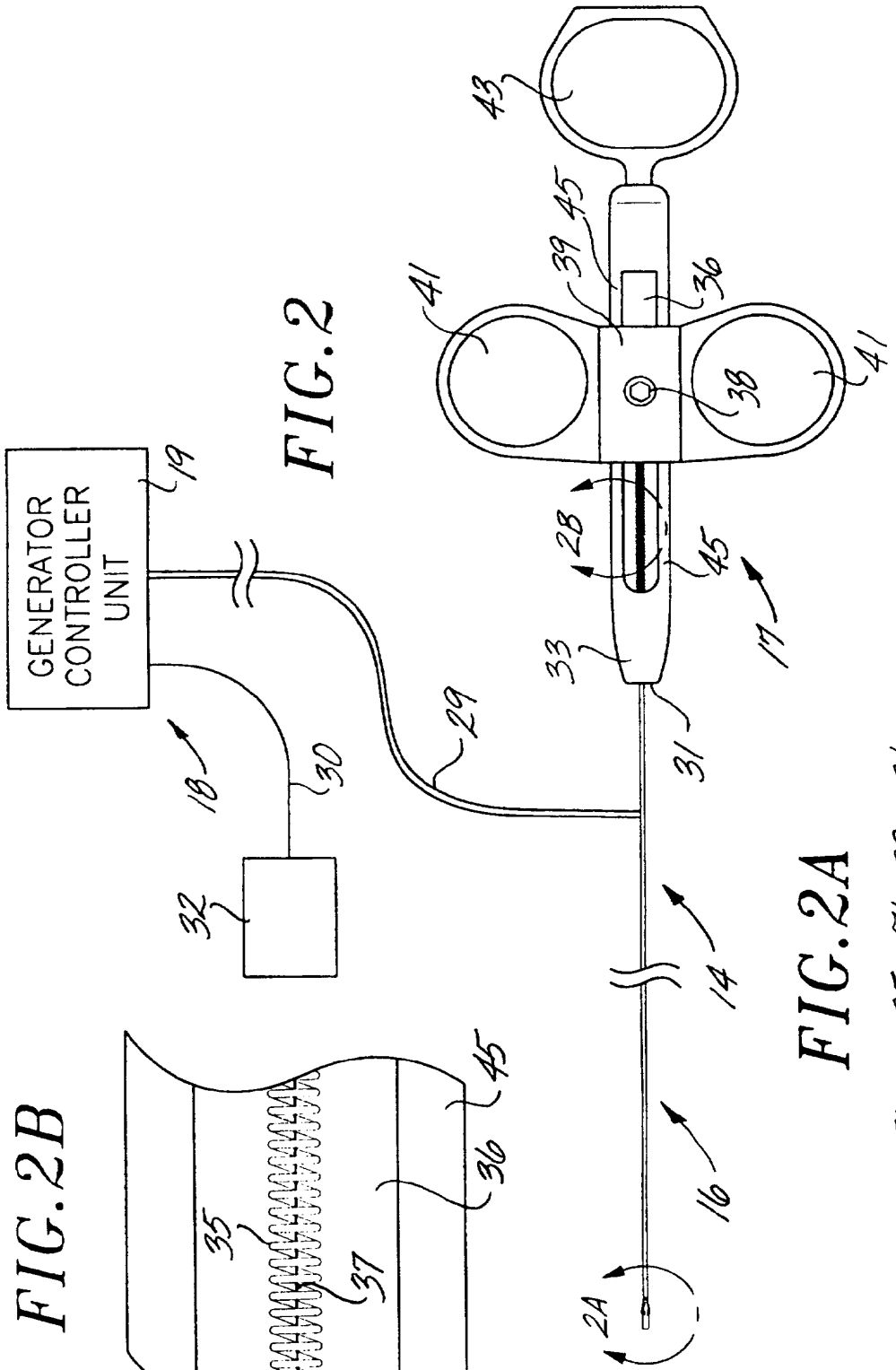


FIG.2

FIG.2B

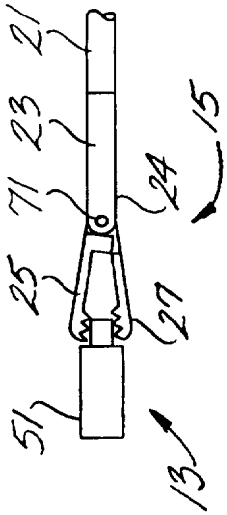


FIG.2A

FIG. 3

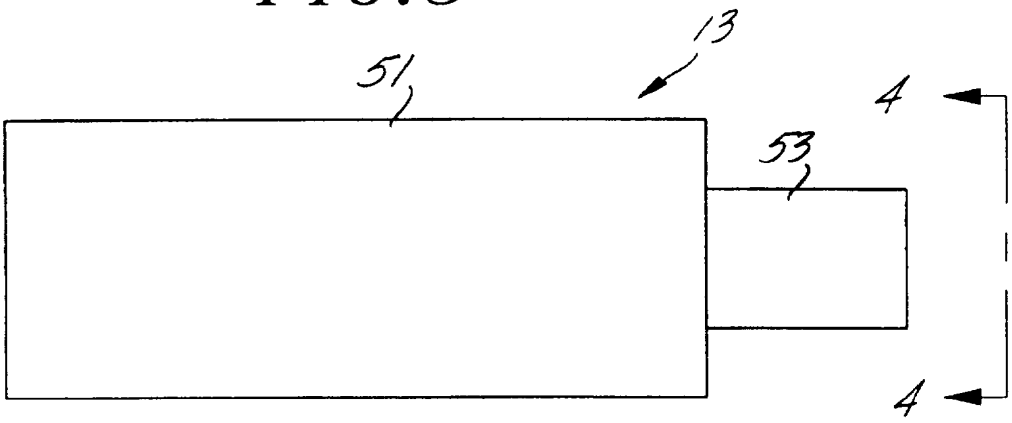


FIG. 4

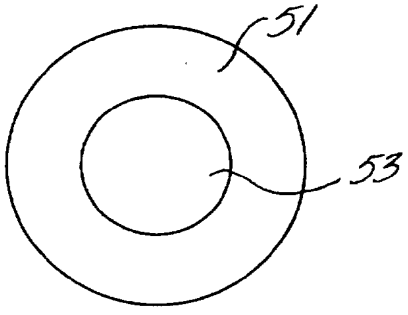
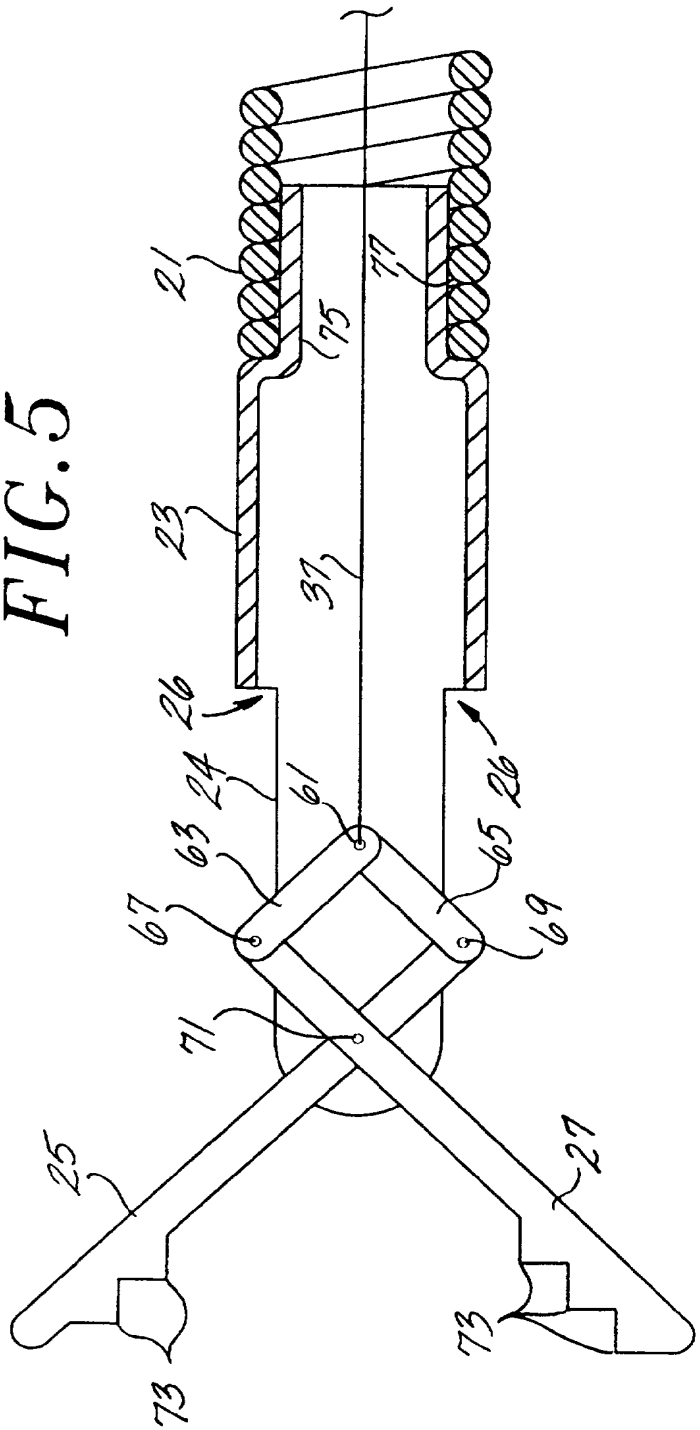


FIG. 5



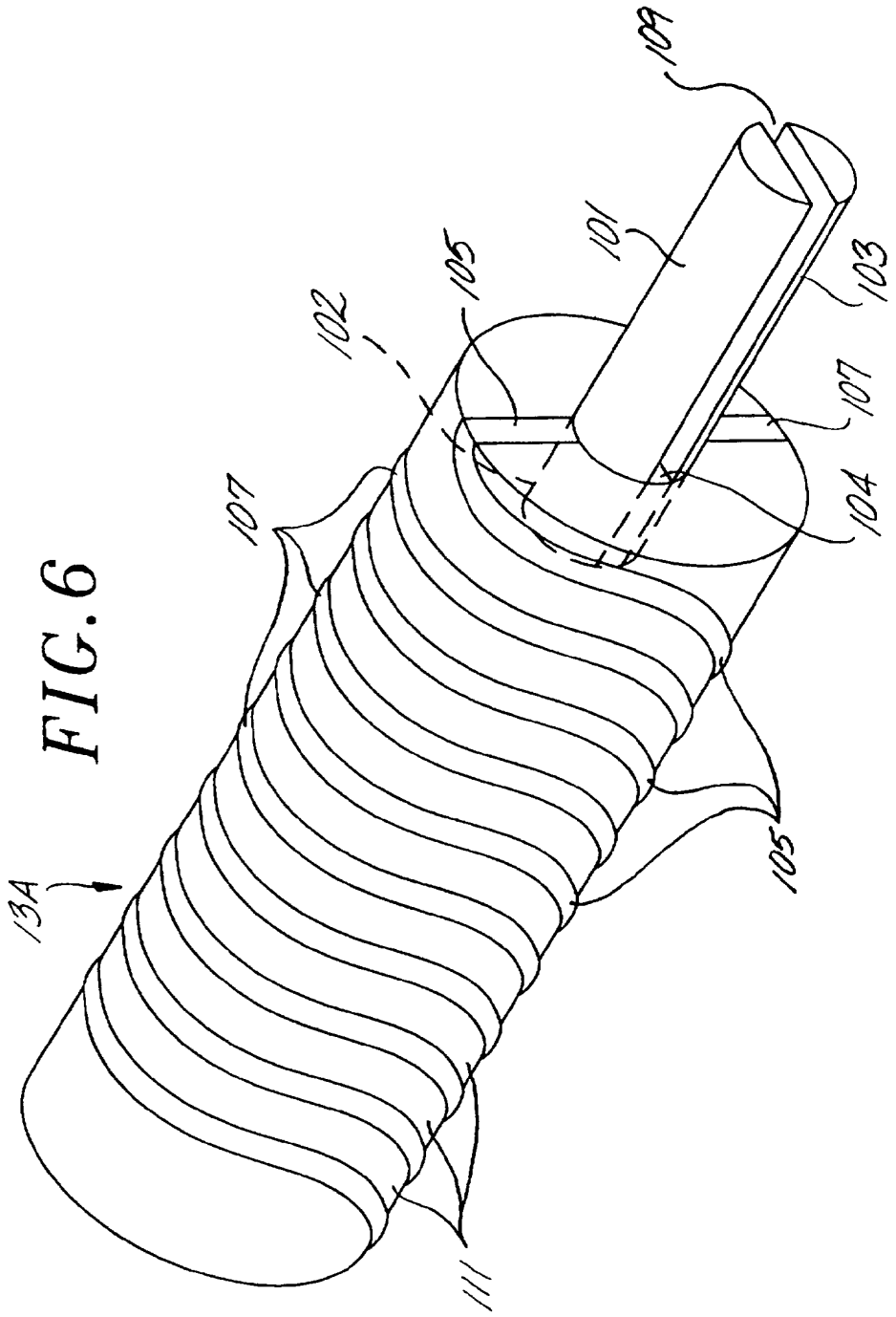


FIG. 6

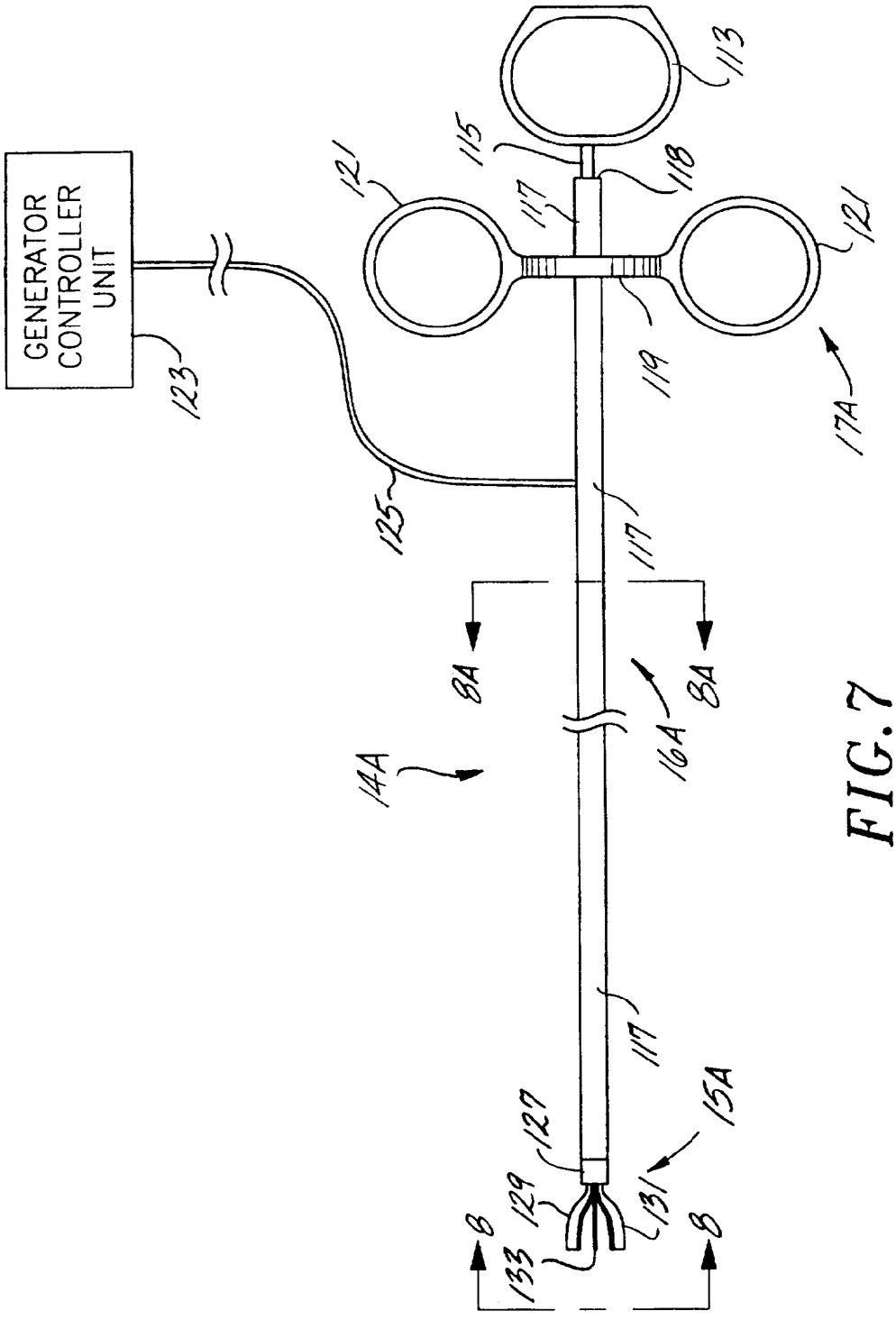

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FIG. 7

FIG. 8

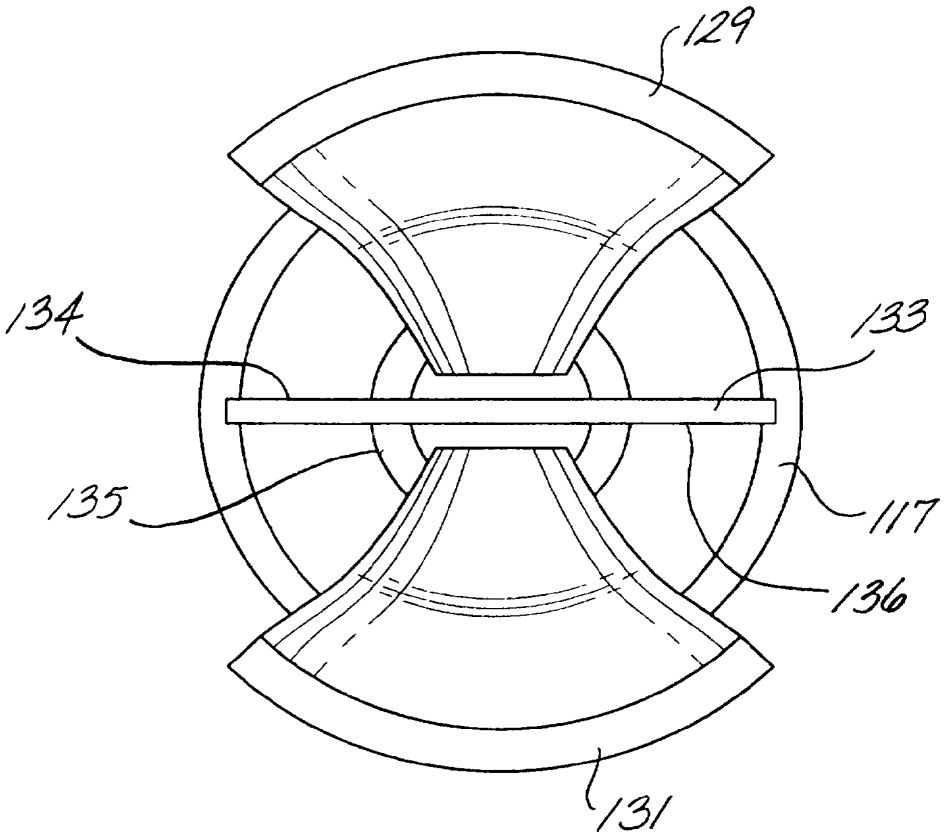
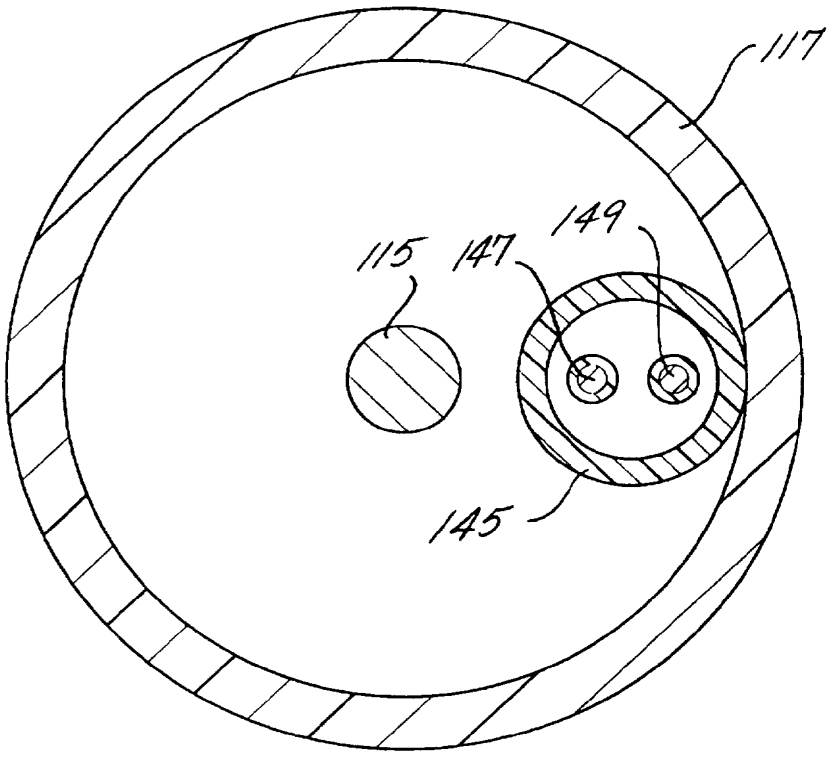


FIG. 8A



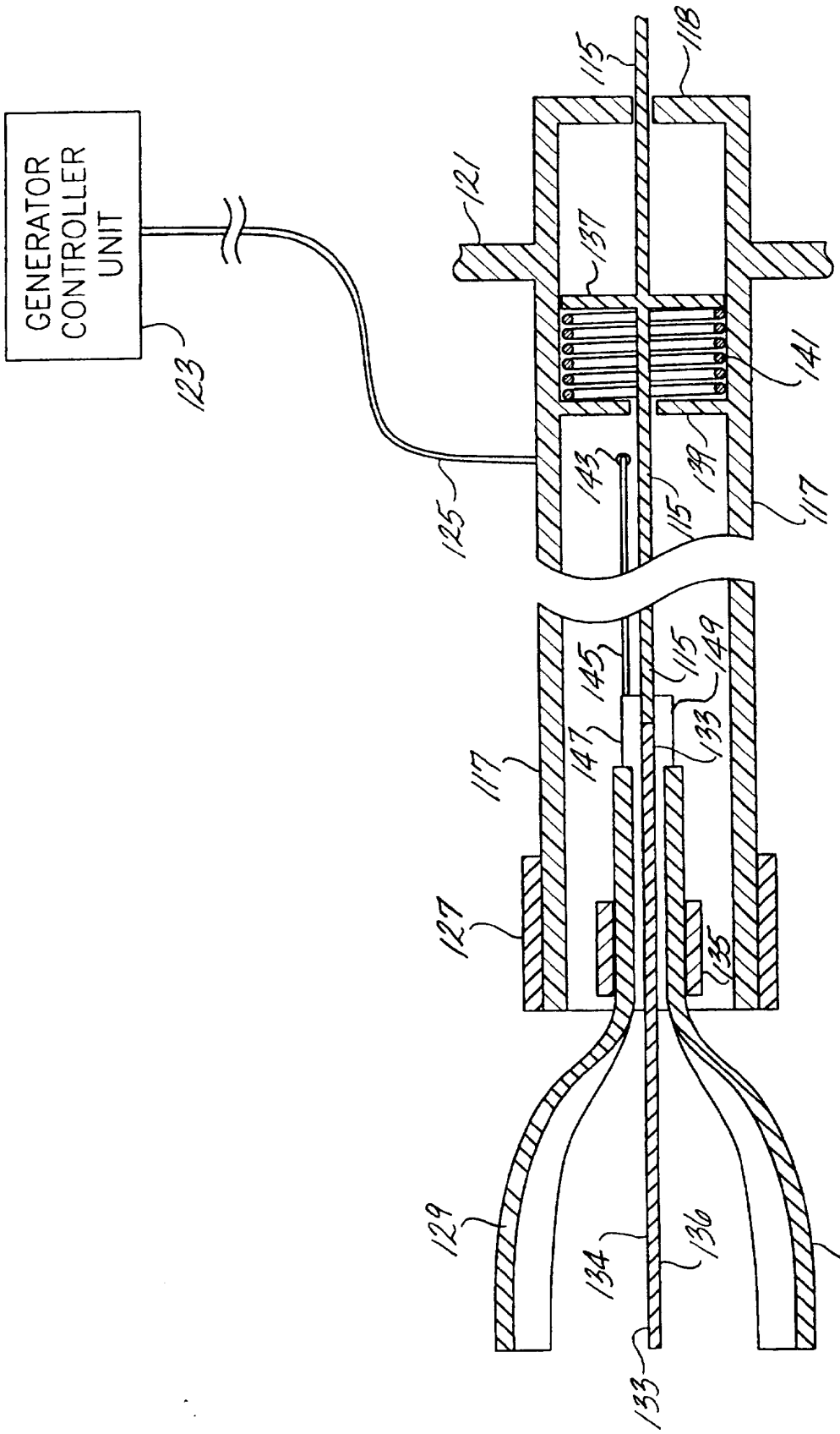

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FIG. 9

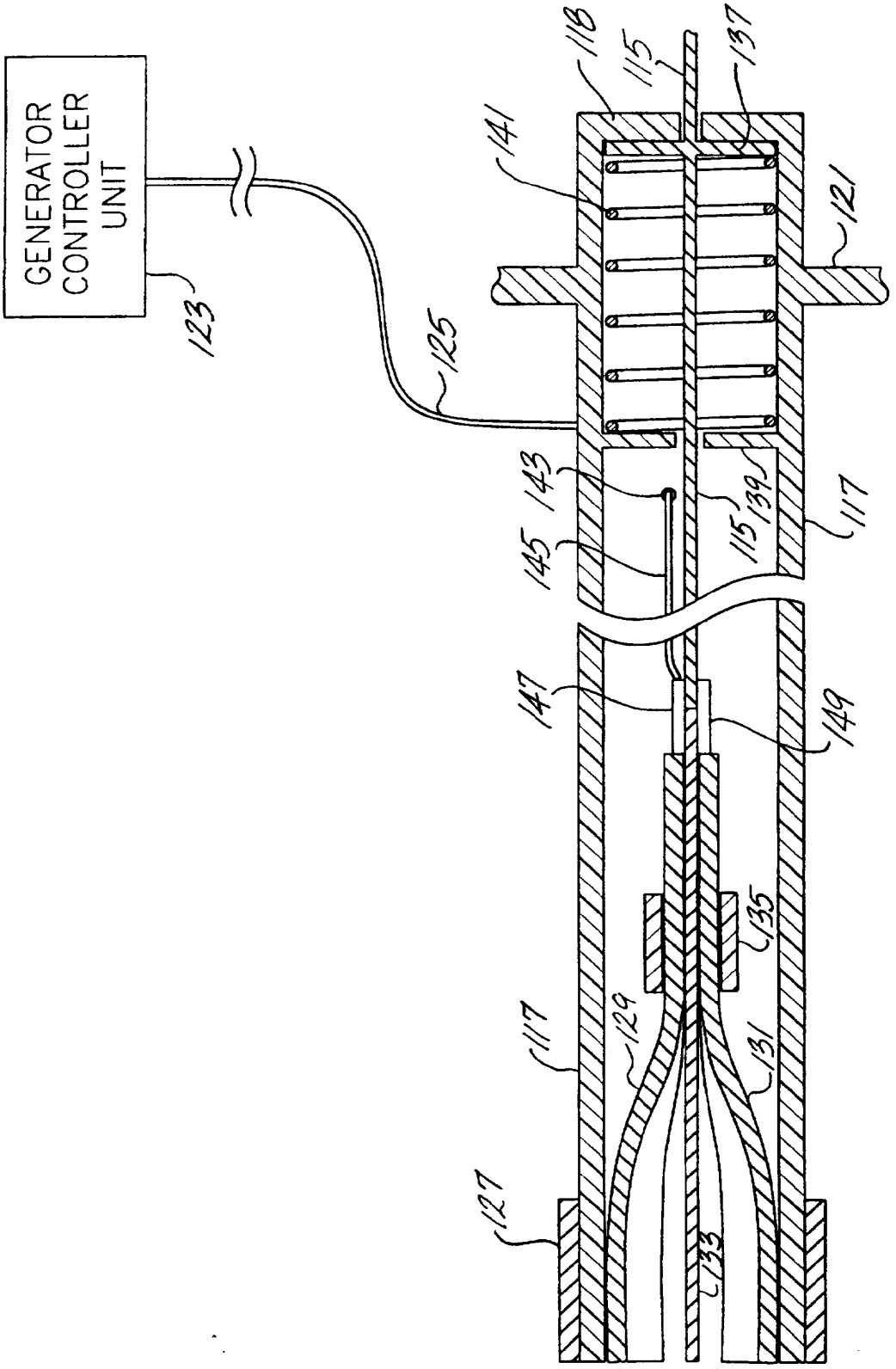
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FIG. 10

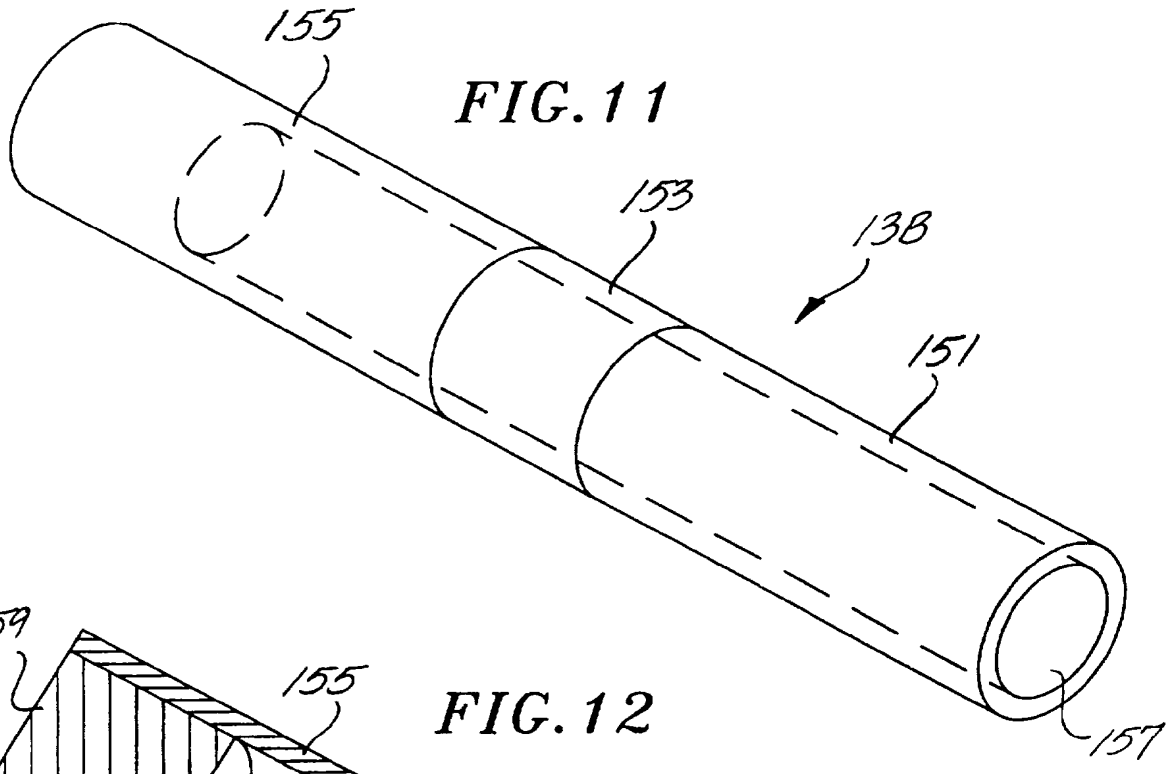


FIG. 11

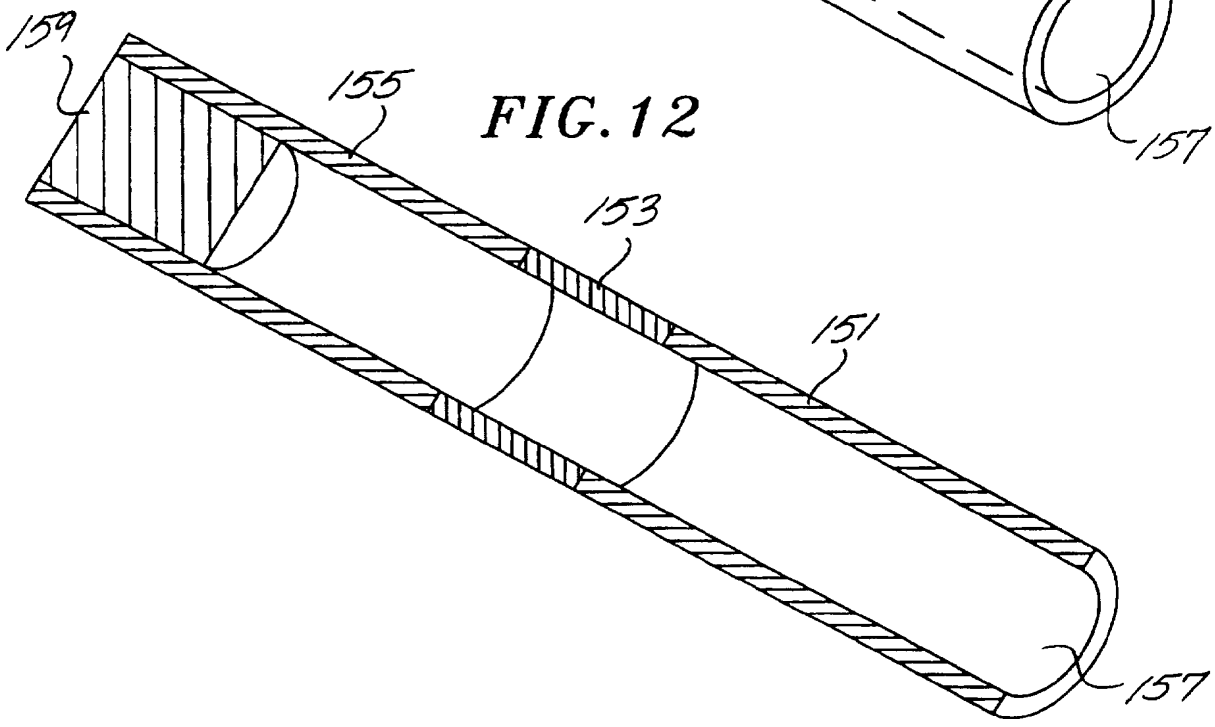


FIG. 12

FIG. 13

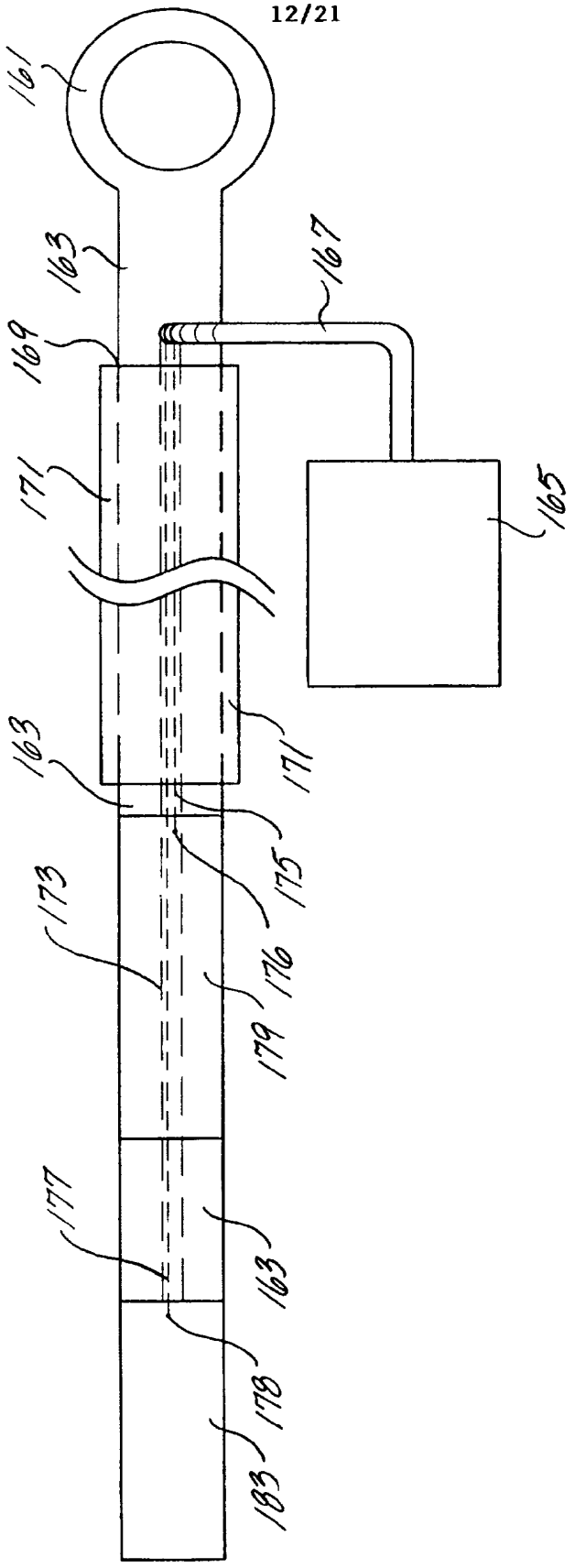


FIG. 14

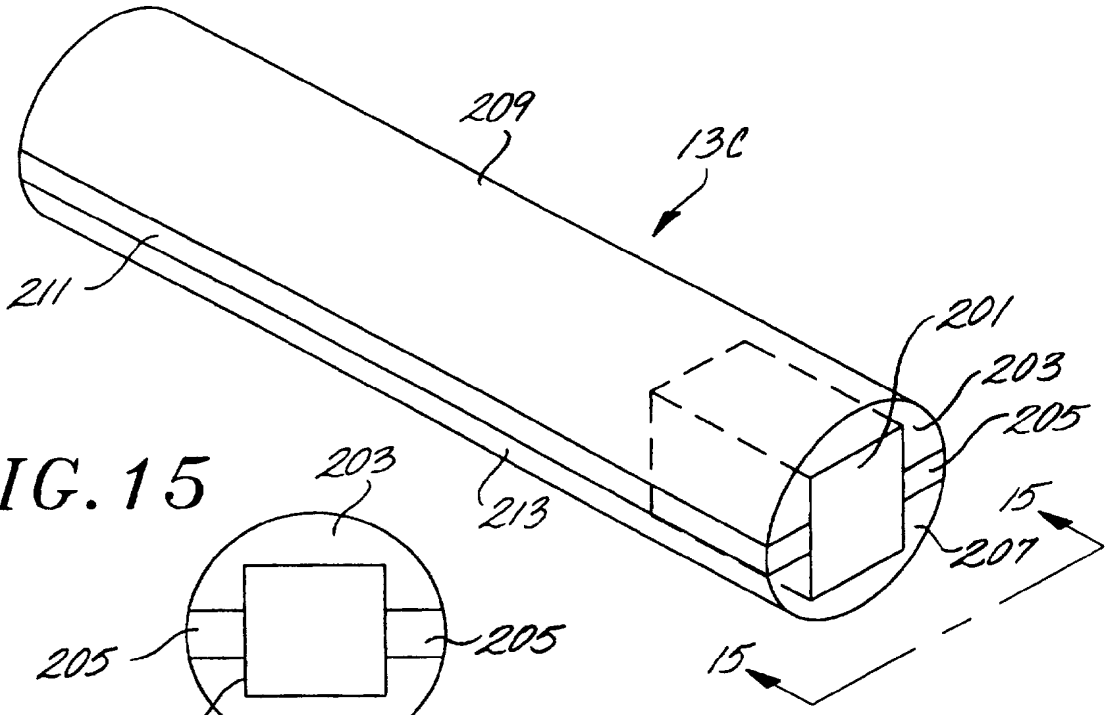


FIG. 15

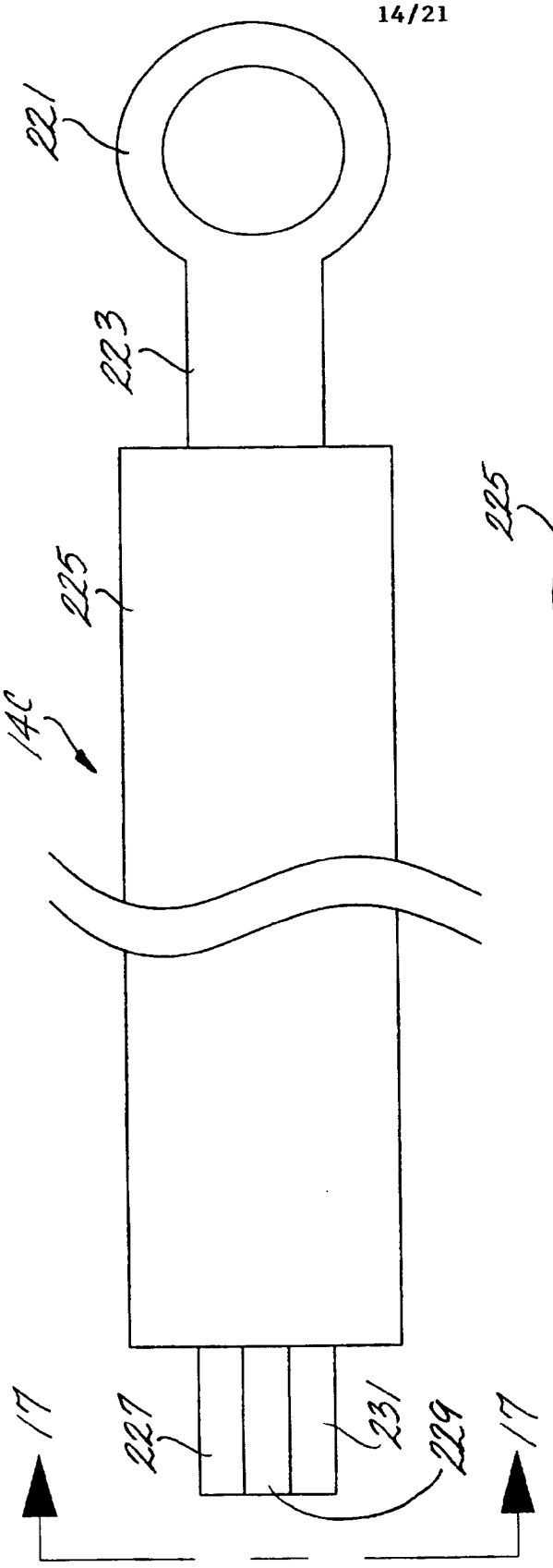


FIG. 16

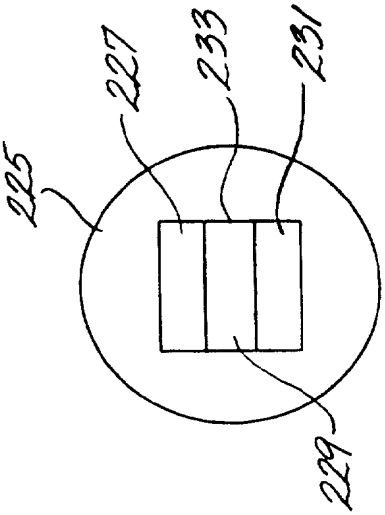


FIG. 17

FIG. 18

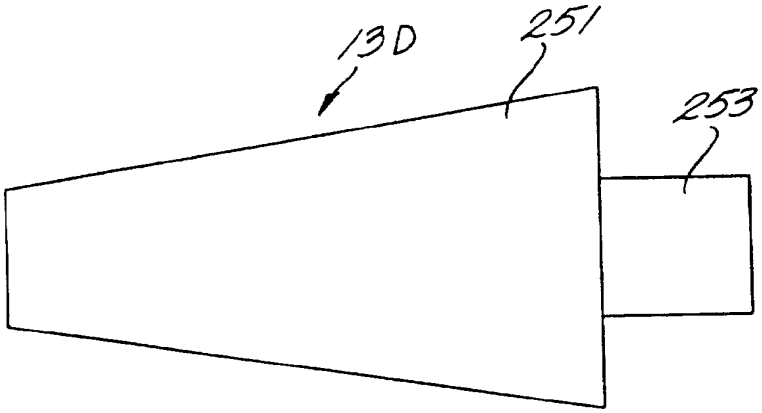
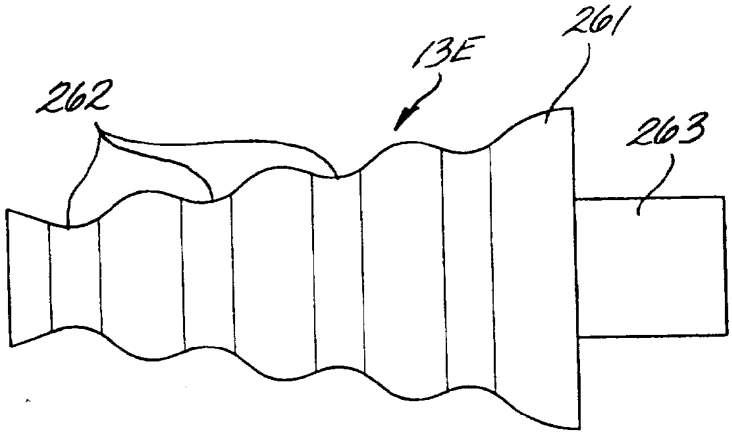
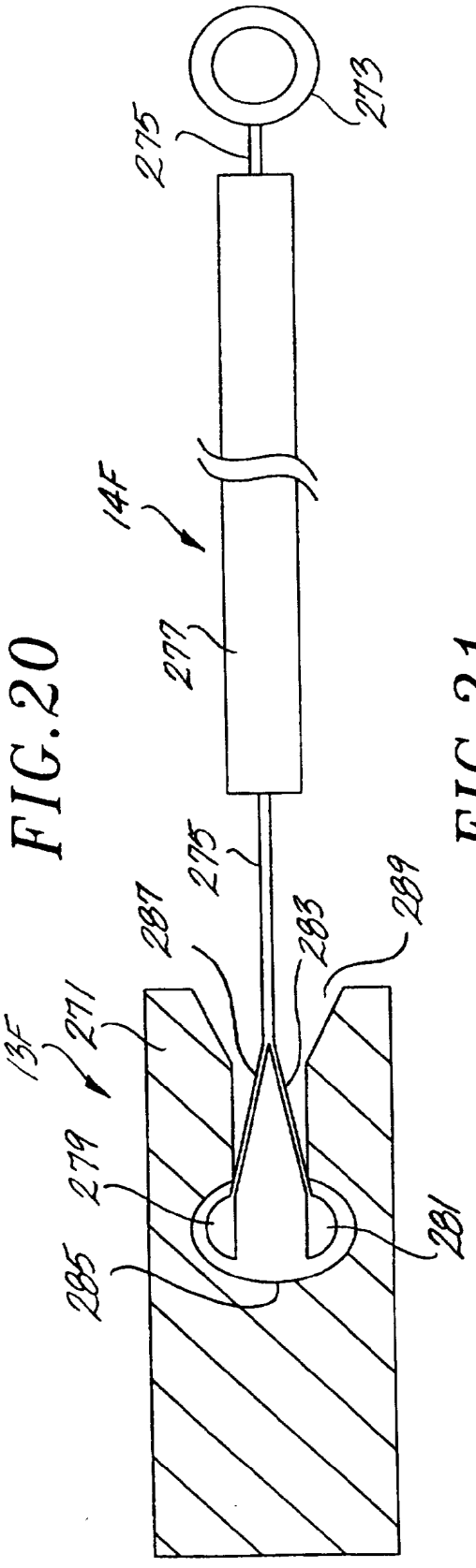


FIG. 19

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13F
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FIG. 20

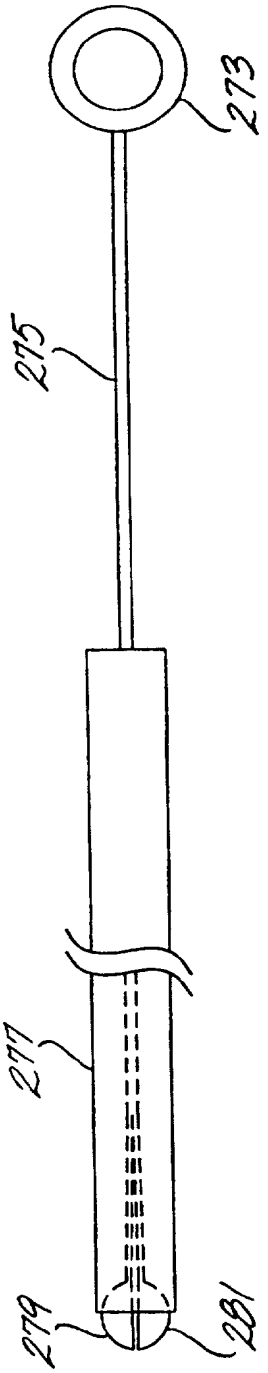
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FIG. 21

FIG.22

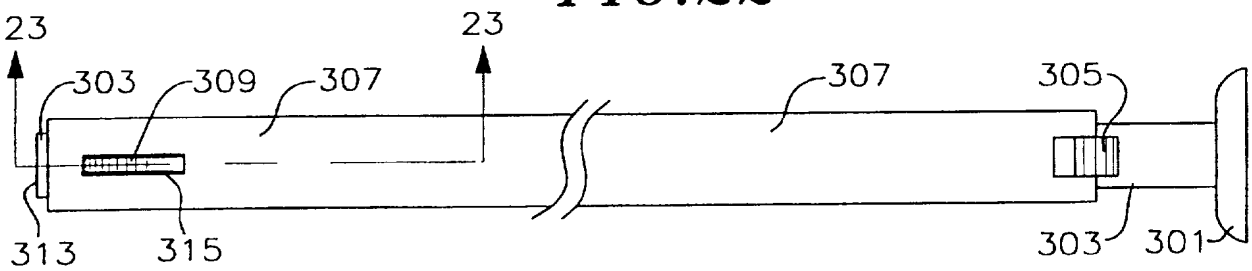


FIG.23

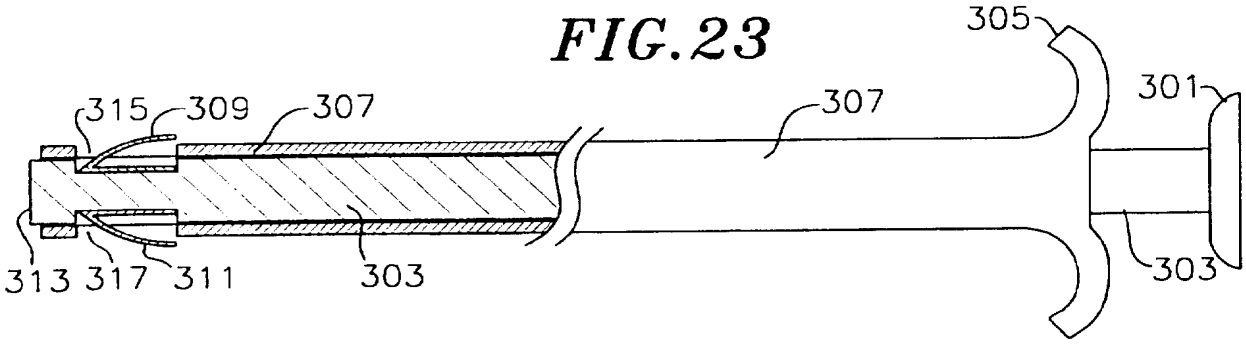


FIG.23A

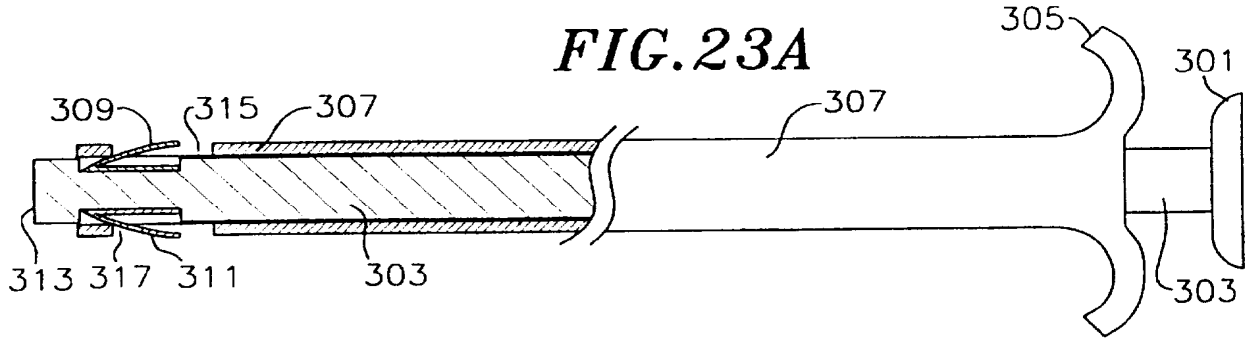


FIG.23B

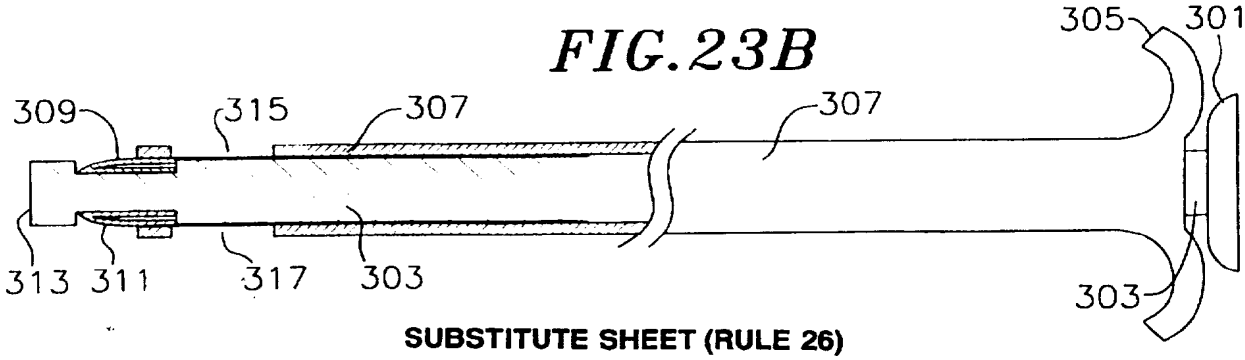


FIG. 24

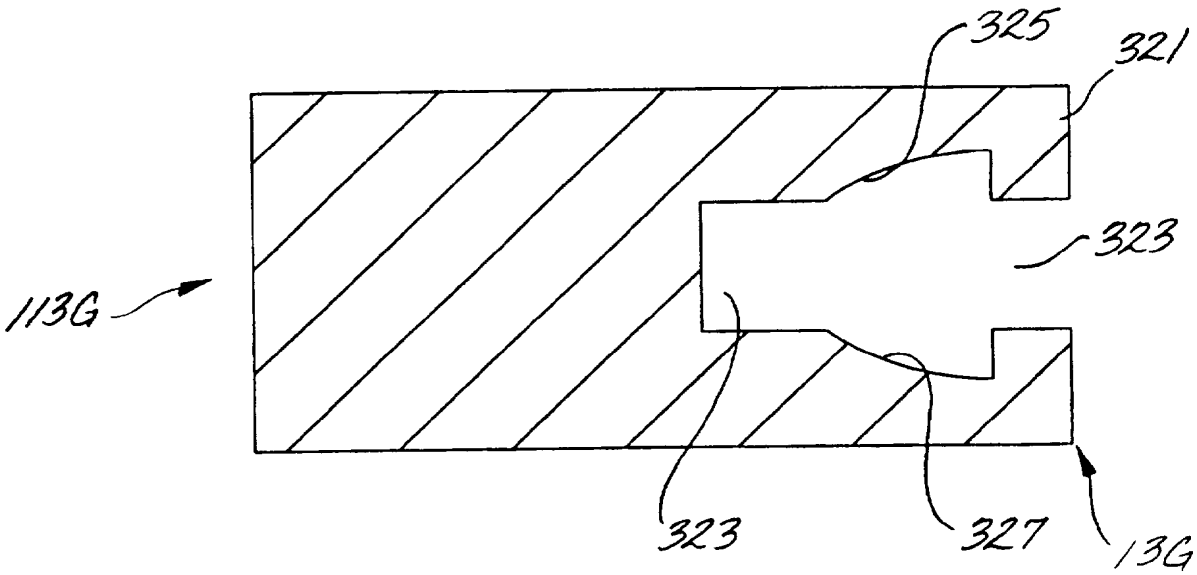
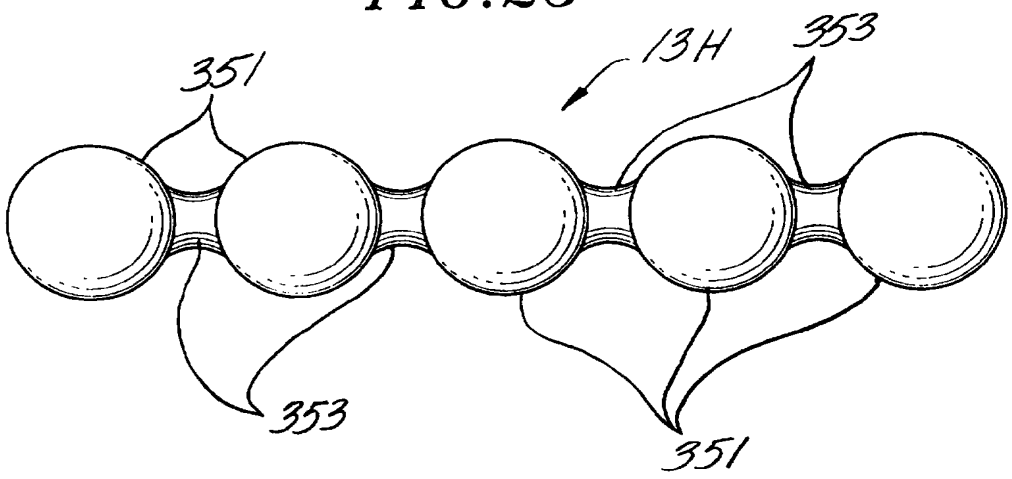


FIG. 25



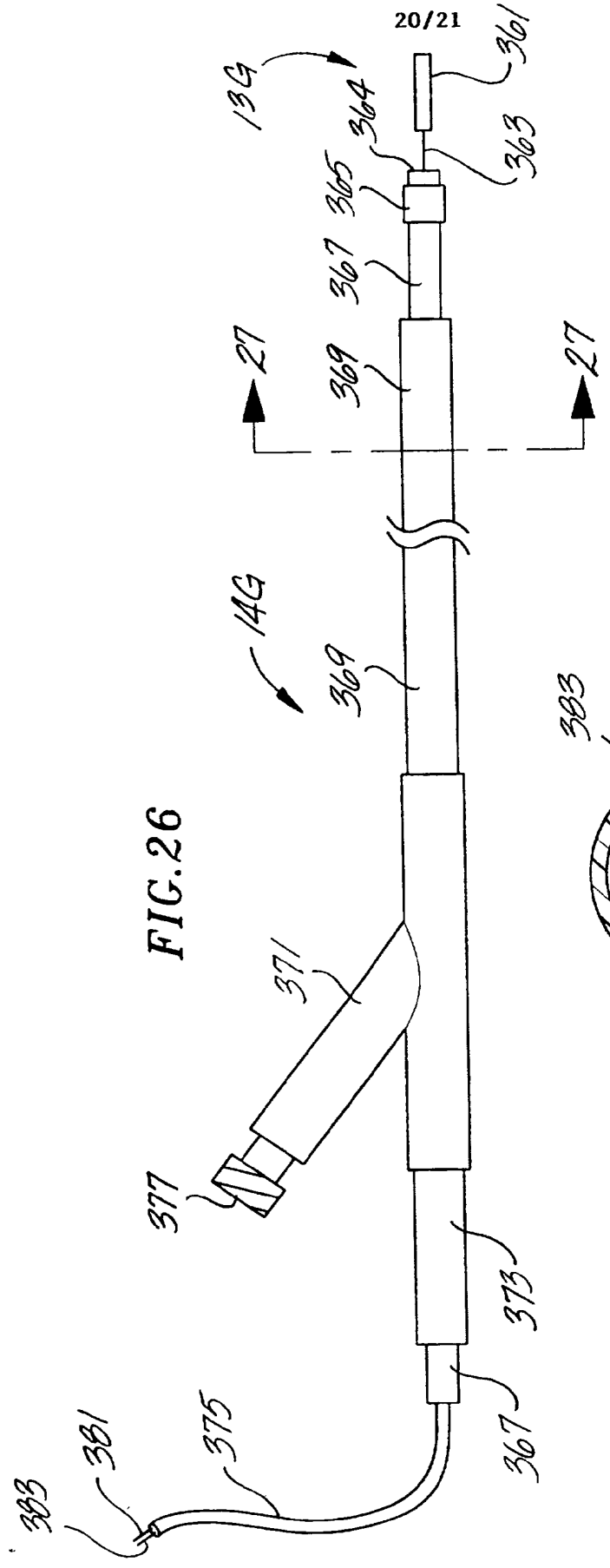

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FIG.26

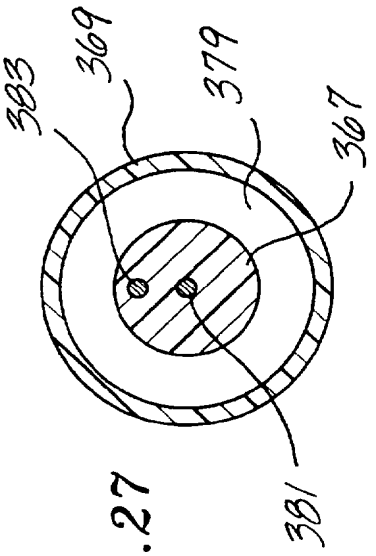
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FIG.27

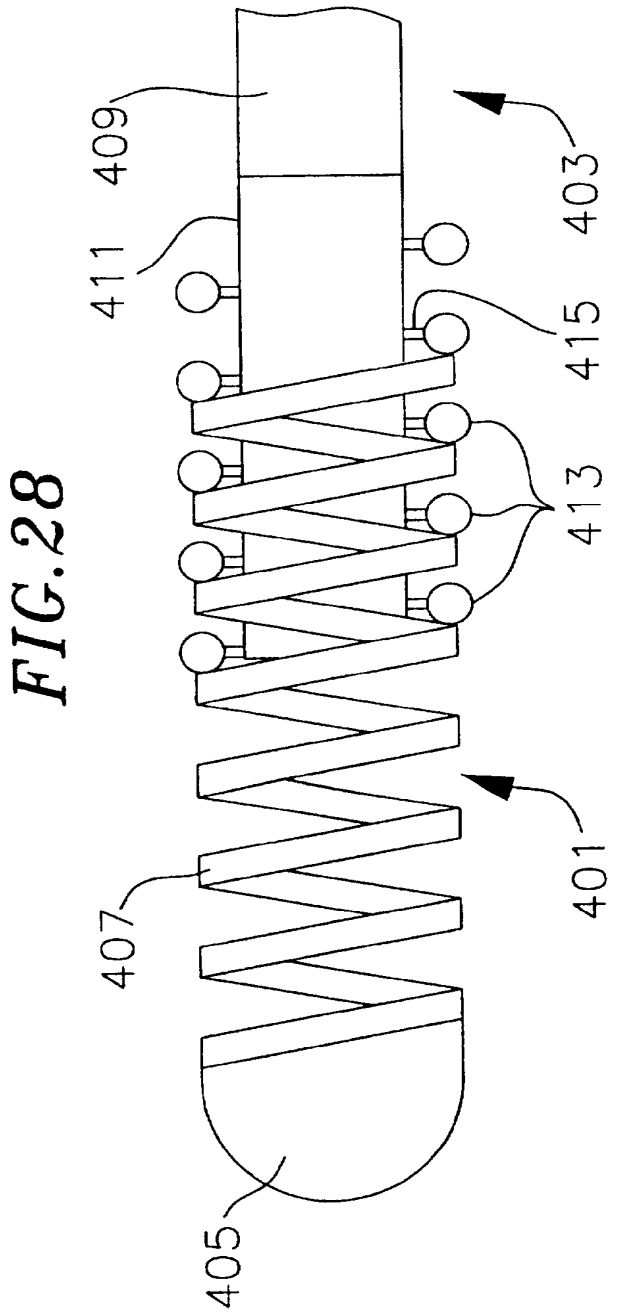

FIG.28

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US97/11268

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 17/36
US CL :606/34, 41, 46

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/34, 40-42, 45-52

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,122,137 A (LENNOX) 16 JUNE 1992, SEE ENTIRE DOCUMENT.	1-21

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 07 OCTOBER 1997	Date of mailing of the international search report 23 OCT 1997
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer FOR DAVID SHAY Telephone No. (703) 308-2215

Form PCT/ISA/210 (second sheet)(July 1992)★